DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Renovis Surgical Technologies
% Rich Jansen, Pharm. D.
President
Silver Pine Consulting, LLC
11821 Bramble Cove Drive
Fort Myers, Florida 33905

February 6, 2015

Re: K143126
Trade/Device Name: Renovis S141 Lumbar Interbody Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: November 11, 2014
Received: November 13, 2014

Dear Dr. Jansen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143126

Device Name
Renovis S141 Lumbar Interbody Cage System

Indications for Use *(Describe)*

The Renovis S141 Lumbar Interbody Cage System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Renovis S141 System implants are to be used with autogenous bone graft. Patients should be skeletally mature and have at least six months of non-operative treatment. The Renovis S141 System must be used with supplemental fixation cleared by FDA for use in the lumbar spine.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY
Renovis S141 Lumbar Interbody Cage System

Date: January 30, 2015

Submitter: Josh Brown
Renovis Surgical Technologies, Inc.
1901 W. Lugonia Ave, Ste 340
Redlands, CA 92374
Telephone: 909-557-2360
Fax: 909-307-8751

Regulatory Contact: Rich Jansen, Pharm. D.
Silver Pine Consulting, LLC
612-281-5505

Product

Trade Name:	Renovis S141 Lumbar Interbody Cage System
Common Name:	Intervertebral Body Fusion Device
Product Class:	Class II
Classification:	888.3080
Product Code:	MAX
Panel Code:	87

Device Description
The Renovis S141 Lumbar Interbody Cage System consist of 3 designs and each design is available in either PEEK or titanium alloy. The PLIF and TLIF implants are available as a lordotic form, while the OLIF implants are provided with no lordosis. The implants are available in various heights and lengths to accommodate patients' anatomy. The implants are provided sterile, and a set of instrument for implantation is provided to facilitate implantation. Two radiographic markers made of tantalum per ASTM F650 are included in the PLIF and OLIF PEEK implants, and three radiographic markers made of tantalum per ASTM F560 are included in the TLIF PEEK implant to allow radiographic visualization.

Predicate Device
The Renovis S141 Lumbar Interbody Cage System is substantially equivalent to legally marketed predicate devices. The primary predicate is the Renovis S134 ALIF cage (K142095) Additional predicate devices are the Ray Threaded Fusion Cage (P950019), Lumbar I/F Cage (P960025), and the K2M Aleutian Spinal System (K133614).

Intended Use / Indications for Use
The Renovis S141 Lumbar Interbody Cage System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar

spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Renovis S141 System implants are to be used with autogenous bone graft. Patients should be skeletally mature and have at least six months of non-operative treatment. The Renovis S141 Cage System must be used with supplemental fixation cleared by FDA for use in the lumbar spine.

Performance Testing
The Renovis S141 Lumbar Interbody Cage System was tested according to ASTM F2077 and ASTM F2267. Testing included static and dynamic axial compression, subsidence and expulsion. Test results demonstrate that the Renovis S141 Lumbar Interbody Cage System is substantially equivalent to the predicate devices.

Summary:
The Renovis S141 Lumbar Interbody Cage System is substantially equivalent to the predicate devices in regards to:

- Indications for Use
- Materials
- Dimensions
- Function
- Mechanical testing

The Renovis S141 Interbody Cage System demonstrates substantial equivalence to the predicate devices based on the non-clinical performance testing.